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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,197	01/30/2006	Rick Haselton	VBT:017US	2125

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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,197	HASELTON ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Decmeber 22, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *40-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 7-39* is/are rejected.

7)☒ Claim(s) *2 and 4-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-39) in the reply filed on December 22, 2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites the limitation "the fiber" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 7-9, 12, 14-23, 25-28 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Huang et al., 7,015,047.

As to claim 1, Huang et al. teach magnetizable microdevices (col. 17, lines 8-9), having binding partners capable of binding to a moiety to be detected (col. 20, lines 25-27), wherein the microdevices are used to bind to a moiety and to manipulate the moiety (col. 34, lines 19-21) and to detect the moiety by detecting the photorecognizable coding patterns, such as barcodes or fluorescence (col. 19, lines 1-7.) For example the microdevices can have antibodies immobilized thereon to capture and bind to target cells (col. 20, lines 49-52.) The microdevices can be rod-shape (col. 43, lines 39-46), which is deemed to be a filament because it has the same shape as a filament, i.e., cylindrical, elongated element. The microdevices are deemed to be traversing through a first chamber, wherein the first chamber contains the target in solution because the microdevices are flowing within a flow system (col. 40, line 3-11.) The binding partner on the microdevices are deemed to be the first probe. The detection step is deemed to be the step of assessing binding.

As to claim 3, Huang et al. teach that the optical labeling substance used is a fluorescence substance or bar code (col. 18, line 64 – col. 19, line 5). The binding partner on the microdevice is deemed to be associated with the fluorescence substance or bar code, i.e., the probe identifier.

As to claim 7, Huang et al. teach a step of collecting the microdevice through an outlet channel. The outlet channel is deemed to be a second chamber, which lacks the target.

As to claims 8 and 9, Huang et al. teach introducing a liquid suspension in order to form an array of microdevice (col. 34, line 59- col. 35, line 13.)

As to claim 12, the probe identifier is a bar code (col. 18, line 64 – col. 19, line 5).

As to claim 14, the bar code is disposed in a linear fashion (see fig. 8 and col. 5, lines 32-39.)

As to claim 15, Huang et al. teach that thermal convection may be used to facilitate liquid mixing (col. 29, lines 11-22.)

As to claim 16, Applicants do not specify what the surface features are and thus the sides of the rod-shape microdevices (col. 43, lines 39-46), which is deemed to be a filament.

As to claim 17, Applicants do not specify what the surface features are and thus the walls of the flow channel are deemed to be the claimed surface features because they enhance mixing by confining the solution.

As to claim 18, the filament is transparent (col. 43, lines 62-65 and lines 42-45.)

As to claim 19, Huang et al. teach that metal films made of gold for example can be incorporated into the microdevices and increase electrical conductivity of the microdevices (col. 14, lines 58-61.)

As to claim 20, the target is subject to electrophoretic movement (col. 12, 1-11).

As to claim 21, the electrophoretic movement promotes target-probe interaction (col. 15, lines 36-44.)

As to claim 22, Huang et al. teach that manipulation of moieties include separation of moieties, using compatible means disclosed, such as electrophoretic (col. 15, lines 24-28.)

As to claim 23, the manipulation of the microdevice through one portion of a channel of flow device is considered to be the first traversing through a chamber, and the manipulation through the next portion of the channel is considered to be the second traversing, since Applicants have not provided any limitations regarding the structure of the chamber.

As to claim 25, the manipulation of the microdevice through the next portion of the channel is considered to be a second traversing in a different chamber.

As to claim 26, Huang et al. teach that directed thermal convection may act as an active force (col. 29, lines 21-22.) Thus, with directed thermal convention, the temperature in one part of the flow system is different from another part.

As to claims 27 and 28, with electrophoresis being the means to manipulate moieties (col. 15, lines 24-28), the charge or voltage in one part of the flow system (i.e., one chamber) is different or altered from that in another part.

As to claim 30, the optical labeling with a fluorescence substance or bar code (col. 18, line 64 – col. 19, line 5) is considered to be enhancing detection of binding of the target to the first immobilized probe.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al., 7,015,047.

As to claim 36, Huang et al. do not disclose the diameter of the rod. However, Huang et al. do teach that the microdevice can be in any suitable shape and dimension and have thickness from about 0.1 micron to about 500 microns (col. 17, lines 37-43.) It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (MPEP 2144.05 IIA, citing *In re Aller*, 105 USPQ 233). In this case, Huang et al. disclose the general conditions of the claim and the diameter of the rod being in the range claimed by Applicant is a workable or optimum range and thus its discovery involves only routine skill in the art.

As to claim 37, Huang et al. also do not disclose the diameter of the processing chamber. However, the diameter claimed by Applicants is within a workable or optimum range and thus its discovery involves only routine skill in the art given that Huang et al. disclose the general conditions of the claim.

As to claim 38, Huang et al. also do not disclose the volume of the target solution, but the range in volume recited by Applicants is within a workable or optimum range and thus its discovery involves only routine skill in the art given that Huang et al. disclose the general conditions of the claim.

As to claim 39, Huang et al. do not teach that the density of the fiber (presumed to be the filament)

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al., 7,015,047, in view of Connell, 3,818,444.

Huang et al. disclose the invention substantially as claimed (see above) except for the bar code being in an annular fashion. Huang et al. rather disclose linear bar codes (see fig. 8).

Connell however teach that the omni-directional reading characteristics of an annular bar code can be read by any directional scanning beam intersecting the common center (col. 1, line 57-61.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a bar code in the Huang et al. microdevice in an annular fashion because Connell disclose that annular bar codes provide the benefit of reading the code in any directional scanning beam intersecting the common center, as would be desirable for convenience.

Claims 24, 29 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al., 7,015,047, in view of Kayyem et al., 2002/0006643.

Huang et al. disclose the invention substantially as claimed except for a second liquid phase probe that binds to the target at a location distinct from the first probe and a third liquid phase probe that is in an inactive state and then activated to facilitate amplification.

As to claims 31-35, Kayyem et al. teach amplification of target nucleic acid sequence using branched or linear conformation and using label probes that hybridize to the amplification sequences (paragraph 0174). As to claims 24 and 29, Kayyem et al. teach repeating amplification steps depending on the sensitivity of the detection (paragraph 0083). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the nucleic acid sequences, and labeling and detection technique disclosed by Kayyem et al. in the Huang et al. invention because Kayyem et al. teach that they provide the benefit of amplification of the target nucleic acid sequence.

Allowable Subject Matter

Claims 2 and 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/18/07

ANN YEN LAM
PATENT EXAMINER